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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/698,454

10/27/2000

Miri Seiberg

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Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/698,454	Applicant(s) SEIBERG ET AL.	
	Examiner YONG S. CHONG	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 18-22 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 18-22 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/25/08, 4/7/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/25/08 has been entered.

Claim(s) 1-14, 17, 23-29 have been cancelled. Claim(s) 15-16, 18-22, 30-34 are pending. Claim(s) 15-16, 18-22 have been amended. Claim(s) 15-16, 18-22, 30-34 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below as a result of the new claim amendments. The following new rejection will also apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the treatment of sunburn, does not reasonably

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provide enablement for *preventing*. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a method of treating and preventing sunburn by administering a composition comprising a non-denatured soy product.

(2) State of the Prior Art: The state of the art regarding treating sunburn is relatively high, however the state of the art for the prevention of sunburn is non-existent.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention, inhibition, and treatment of sunburn by administering a composition comprising any non-denatured soy product having trypsin inhibitory activity.

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(4) Guidance of the Specification: The guidance of the specification as to the prevention of sunburn is completely lacking. The specification discloses preventing the onset of sunburn. However, the specification fails to mention how one is able to determine whether the onset of sunburn in a subject would have occurred in the absence of treatment, thus being unable to confirm that prevention has indeed taken place. Moreover, the specification fails to mention the complete prevention or cessation of sunburn once the onset of preclinically evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating, inhibiting, and preventing sunburn. The specification does not disclose how one of ordinary skill in the art at the time of the invention would be able to prevent sunburn, nor does the prior art reveal any type of prevention associated with sunburn.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent sunburn. Moreover, one is unable to determine whether a subject will ever develop a sunburn should this subject be administered the non-denatured soy product.

(7) Working Examples: The specification does not give any data for the prevention of sunburn.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of sunburn. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation

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for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim(s) 22 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Kelly et al. (WO 99/36050, of record).

Kelly et al. teach using soy extract for protecting skin from UV damage (abstract). The soy extract of Kelly et al. is obtained by the extraction with a mixture of organic solvents and water (pg. 11, lines 23-27). The recitation of “non-denatured” soy product is inherent in the reference because soy beans are extracted without using enzymes and/or temperature. The compositions of Kelly et al. may also contain preservatives (pg. 10, lines 8-9). Examiner notes that Kelly et al. teach that the ratio of organic solvent in water may be as low as 0.1%. It is highly unlikely that 0.1% of ethanol in water will cause protein denaturing. Moreover, the soy extract containing compositions herein possess the same skin protecting or trypsin inhibitory activity as claimed because a composition and its properties are inherent. Applicant has not differentiated between soy beans that have or do not have this property by their structure or process steps.

Response to Arguments

Applicants argue that nowhere does Kelly et al. describe explicitly or suggest non-denatured soy extracts containing soy trypsin inhibitory (STI) activity as being useful in topical compositions. Applicants point out that the soy extract of Kelly et al. would not contain STI. As set forth in the Seiberg Declaration, soybean extract obtained by extraction with a mixture of organic solvents and water will not contain STI. Since STI is water-soluble, it would not enter the organic phase, but the aqueous phase, which is removed in the Kelly et al. procedure. Even if STI were present in the organic phase, it would be denatured by the presence of organic solvents, as set forth in the accompanying Seiberg Declaration.

The Seiberg Declaration under 37 CFR 1.132 filed on 9/29/08 is insufficient to overcome the rejection of claims 22 and 34 based upon Kelly et al. (WO 99/36050, of record) as set forth in the last Office action because none of the cited references in the Declaration, with the exception of Benedek et al., even mention soy products. The general reference to proteins cannot support a specific case regarding soy products. The Benedek et al. reference merely teaches a slow denaturing process of 15 minutes (half life) upon extraction with 1-propanol and no other solvent. This is not persuasive because most extractions are completed within 15 minutes, therefore resulting in the majority of soy products as not denatured. Furthermore, there is no generalization of organic solvents denaturing soy products nor does 1-propanol support a case for all known organic solvents. Therefore, it is Examiner's position that the pharmaceutical

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composition taught by Kelly et al. comprising soy extract is not denatured nor is it devoid of STI activity.

Examiner also notes that neither the Kelly nor the WO 93/23069 references claim to have denatured soy bean extract. Nowhere in the extraction methods do both references state the use of enzymes, temperature, or acids, which are well-known methods of denaturing proteins. The denaturing of soy beans so as not to contain soy trypsin inhibitor proteins are merely a conjecture on the part of the Applicants, which are not supported by factual evidence.

The Kelly et al. reference states that soy may be extracted with a mixture of organic solvents such as ethanol, chloroform, acetone, ethyl acetate, and water (col. 11, lines 23-27). There is no mention of 1-propanol in the list of solvents used by Kelly et al. Furthermore, Applicant's specification states that soybeans can be extracted with an ethanol/water mixture in a way that the STI activity is still retained (pg. 8, lines 1-5). Examiner notes that Kelly et al. also teach an extraction using an ethanol/water mixture. How is it that the soy product is denatured in the Kelly et al. process and not denatured in Applicant's claimed process when the extraction method is essentially the same? Applicant is requested to show factual evidence and not circumstantial evidence that the cited prior art methods results in a denatured soy product devoid of STI activity.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

The Lin Declaration under 37 CFR 1.132 filed on 9/29/08 is insufficient to overcome the rejection of claims 22 and 34 based upon Kelly et al. (WO 99/36050, of

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record) as set forth in the last Office action because the Declaration states nothing with respect to the Kelly reference. There is no side-by-side comparison with the closest prior art that is commensurate with the scope of the claims. In fact, the Declaration merely states the differences between denatured and non-denatured soybean extracts in molecular pathways. There is no factual evidence in the Declaration that shows that the extraction procedure in Kelly et al. results in a denatured soy extract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 15-16, 18-21, 30-33 are rejected under 35 U.S.C. 103(a) as being obvious over Tokuyama (JP 5-320061, translation of record) in view of Mizue (JP 62-36304, of record).

The instant claims are directed to a method of evening skin tone and texture, treating acne, increasing elasticity and firmness, reducing the shine and oiliness, treating cellulite of a mammal by administering a composition comprising non-denatured soy product and a stabilizing system.

Tokuyama teach using aqueous or organic extract of soy beans and/or other legumes in unaltered form in topical dermatological compositions for treating a variety of skin diseases and conditions such as scratches, cuts, burns, rashes, eruptions, pimples, blackheads, chapping skin, eczema, dermatitis, etc. (abstract, sections 0009, 0010, 0033, 0035, and Table 4). Moreover, the soy bean extracts applied to the skin as cosmetic products showed “a smoothing effect on the texture of the skin,” “a wrinkle stretching rejuvenating effect,” “skin softening and moisturizing effect,” and “an aging preventing effect” (sections 0045-0047).

Examiner notes that the term “beautifying effect” is often used in Japanese publications as synonymous to “skin whitening effect.” With respect to the limitations “non-denatured” and “having trypsin inhibitory activity,” the Tokuyama reference teaches the same extraction method as disclosed in the instant application (Examples 2-3). Therefore, the soy product of Tokuyama is inherently non-denatured and possesses trypsin inhibitory activity.

“Products of identical chemical composition can not have mutual exclusive properties.” Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical

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chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Furthermore, Examiner notes that the limitations regarding process at which the soy product is made is given little patentable weight since the claims are drawn to a method of using the composition comprising the soy product.

It is respectfully pointed out that even though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorp*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

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However, Tokuyama fail to explicitly disclose the stabilizing system of the instant claims.

Mizue teach stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA (pg. 6 of translation and Examples).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to modify the cosmetic or dermatological soy extract containing compositions of Tokuyama by adding a stabilizing agent, such as a preservative.

A person of ordinary skill in the art would have been motivated to do this to prevent spoilage of the soy extract as suggested by Mizue.

Response to Arguments

Applicant applies the same arguments with respect to Kelly et al. in the obviousness rejection regarding Tokuyama.

This is not persuasive because the arguments against Applicant's assertion also apply here. Tokuyama does not recite that its soy beans are denatured. Tokuyama does not disclose extraction techniques involving high temperatures or acids that cause denaturing; therefore all of the inherent properties of soy beans, including STI's protease inhibitory activity, are present. Furthermore, Examiner reminds Applicant that the specification clearly defines "denaturation" as a loss of enzyme activity (pg. 7, first paragraph). If this were the case with Tokuyama, the soy beans would not possess any

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enzyme activity. This is not the case, as Tokuyama clearly recites that "black soybeans" possess "tyrosinase inhibitory activity" in Table 1. Therefore, the soy beans recited in Tokuyama are not denatured and inherently possess STI's protease inhibitory activity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/YONG S. CHONG/
Primary Examiner, Art Unit 1617
YSC